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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,860	10/07/2003	Marie-Helene Blondelet-Rouault	FRAV2002/0028 US NP	7731
5487	7590	01/29/2009		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 01/29/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/680,860	Applicant(s) BLONDELET-ROUAULT ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,13-16,21,67,72-77 and 94-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,13-16,21,67,72-77 and 94-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the office action mailed on August 21, 2008 on November 11, 2008 is acknowledged.

Claim Disposition

2. Claims 1, 5, 13-16, 21, 67, 72-77 and 94-98 are pending and under examination.

NOTE: The instant claims have been amended to recite "SEQ ID NOS:111 and 141 and sequences that differ from these due to the degeneracy of the genetic code", this language is interpreted as reading on the elected invention of SEQ ID NO:13 (election on August 8, 2006 without traverse), thus the art rejection of record pertaining to SEQ ID NO:13 remains.

Claim Objection

3. Claims 1, 5, 13-16, 21, 67, 72-77 and 94-98 are objected to because of the following informalities:

Claims 1, 5, 13-16, 21, 67, 72-77 and 94-98 are objected to because the claims recite non-elected subject matter.

Correction is required.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 5, 13-16, 21, 67, 72-77 and 94-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a polynucleotide encoding a polypeptide of the spiramycin biosynthesis pathway, said polynucleotide is...(a) SEQ ID NO:111 and 141, and (b) selected from sequences that differ from these sequences due to the degeneracy of the genetic code (see for example claim 1). The specification lacks adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention which encompasses a genus of sequences that could differ from SEQ ID NO:111 and 141. Thus, no correlation is made between structure and function, thus the claimed invention is not adequately described.

Additionally, the claims are drawn to deposited material, however, the instant specification does not have all the required deposit information. The specification discloses that

Art Unit: 1652

said material is a part of the claimed invention, see for example claim 72. Thus use of the claimed invention requires deposited material, but deposit of material does not ensure that it will readily be available during the duration of the patent. Applicant's deposit would satisfy the enablement requirements of 35 U.S.C. 112, provided that the following conditions are met. It is noted that the specification on paragraphs such as [0376, 0298 and 0059] discuss deposit at ATCC and Collection Nationale, however, no information regarding public availability is provided or if the deposit was made under the Budapest Treaty. Thus, the invention is not adequately described and one skilled in the art would not have access to the necessary materials to be able to practice the claimed invention. Applicant makes reference to the deposit number, however, this is not sufficient to illustrate that the information is publicly available or give the assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required. For further information concerning deposit practice, applicants attention is directed to *In re Lundark* 773 F 2d 1216 227 USPQ CCAFC and 37 CFR 1.801-1.809.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claimed genus of polynucleotides could encode non-functional proteins or proteins with a different function than the one described. Based on the unlimited variations contemplated one skilled in the art would at best expect a protein that is different or at worst a protein that is not functional.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere

Art Unit: 1652

statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 95 and 98 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 95 lacks clear antecedent basis for " at least one vector as claimed in claim 14" since claim 14 only recites a "vector". See also claim 98 which has similar language.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara et al. (Accession No. E06690, September 29, 1997, see attached alignment), based on the broad recitation of a sequence that differs from sequences 111 or 141.

Hara et al. disclose a nucleic acid sequence that is 63.8% identical to the claimed SEQ ID NO:13, which reads on the claimed recitation of a sequence derived from SEQ ID NOS:111 or 141. Therefore, the limitation of the claims is met by the reference.

Response to Applicant's Arguments:

7. Applicant's arguments have been considered. Note however, that the art rejection of record and 112 first and second paragraphs remain, however, the rejections of record have been amended. With regard to the 112, first paragraph rejection applicant states that the “derived” language has been withdrawn, however, the claims still read on a genus of nucleic acids (to include the elected invention of SEQ ID NO:13). The claims recite language such as “one of the sequences that differ” which acknowledges that the claims encompasses several nucleic acid structures which are not adequately described. As applicant has received an examination on the record of the elected subject matter it is suggested that the claims are amended to specifically recite that. If applicant can demonstrate by an alignment a substantial overlap between SEQ ID NOS: 13, 111 and 141, then a rejoinder of these sequences is possible, however, the claims would have to be limited to said structures. Applicant should be mindful that the election on record was not a species election and was not traversed. As the claims encompass a genus as set forth above (including newly submitted claims, for example, claim 96 recites, “a recombinant DNA which comprises SEQ ID NO:141” which reads on a large variable genus with the open

Art Unit: 1652

language), the rejection remains. The deposit information remains rejected under 112, first paragraph. Applicant state that a miscellaneous letter coming in would address that, however, to date no information has been received in the office to satisfy the missing deposit information.

Note that the previous rejection under 35 USC 112, second paragraph has been withdrawn, however, a new rejection under this statute has been instituted for the reasons set forth above.

Applicant state that the art rejection of record was based on the “derived language”, note however, that the art rejection of record remains, although the rejection as been amended based on amendments made to the claims and the large variable genus encompassed in the claim language.

Conclusion

8. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652